



DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2012-0081]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillators

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of denials of exemption applications.

SUMMARY: FMCSA announces its decision to deny applications from 14 of 15 individuals seeking exemptions from the Federal cardiovascular standard applicable to interstate truck and bus drivers and the reasons for the denials. The Agency reviewed the medical information of each the individuals who applied for an implantable cardioverter defibrillator (ICD) exemption. Because the medical information received from the cardiologist concerning one individual indicates the ICD has been disabled due to improvement of his heart function, the exemption is no longer needed to operate commercial motor vehicles (CMVs) in interstate commerce. Based on a review of the applications and following an opportunity for public comment, FMCSA has concluded that the remaining 14 individuals in the notice did not demonstrate they could achieve a level of safety that is equivalent to, or greater than, the level of safety that would be obtained by complying with the regulation.

DATES: Denial letters were sent to each of the individuals listed in this notice on July 24, 2015.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief Medical Programs Division, 202-366-4001, U.S. Department of Transportation, FMCSA,

1200 New Jersey Avenue, S.E., Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds “such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.” FMCSA can renew exemptions at the end of each 2-year period.

On April 21, 2015, FMCSA published for public notice and comment, FMCSA 2012-0081 listing 15 individuals seeking exemptions for ICDs. Accordingly, the Agency has evaluated each applicant’s request to determine whether granting an exemption will achieve the required level of safety mandated by statute.

Evaluation Criteria- Cardiovascular Medical Standard and Advisory Criteria

The individuals included in this notice have requested an exemption from the provisions of 49 CFR 391.41(b)(4), which applies to drivers who operate CMVs in interstate commerce, as defined in 49 CFR 390.5. Section 391.41(b)(4) states that:

“...a person is physically qualified to drive a commercial motor vehicle if that person has no current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope (temporary loss of consciousness due to a sudden decline in blood flow to the brain), dyspnea (shortness of breath), collapse, or congestive cardiac failure.”

The FMCSA provides medical advisory criteria as recommendations for use by medical examiners in determining whether drivers with certain medical conditions, procedures, and/or treatments should be certified to operate CMVs in interstate commerce in accordance with the various physical qualification standards in 49 CFR part 391, subpart E. The advisory criteria are currently set out as part of the medical examination report published with 49 CFR 391.43. The advisory criteria for section 391.41(b)(4) provide that:

The term “has no current clinical diagnosis of” is specifically designed to encompass: “*a clinical diagnosis of*” (1) a current cardiovascular condition, or (2) a cardiovascular condition which has not fully stabilized regardless of the time limit. The term “*known to be accompanied by*” is designed to include a clinical diagnosis of a cardiovascular disease (1) which is accompanied by symptoms of syncope, dyspnea, collapse or congestive cardiac failure; and/or (2) which is likely to cause syncope, dyspnea, collapse, or congestive cardiac failure. It is the intent of the FMCSRs to render unqualified, a driver who has a current cardiovascular disease which is accompanied by and/or likely to cause symptoms of syncope, dyspnea, collapse, or congestive cardiac failure. However, the subjective decision of whether the nature and severity of an individual’s condition will likely cause symptoms of cardiovascular insufficiency is on an individual basis and qualification rests with the medical examiner and the motor carrier.

In the case of persons with ICDs, the underlying condition for which the ICD was implanted places the individual at high risk for syncope (a transient loss of consciousness) or other unpredictable events known to result in gradual or sudden incapacitation. ICDs may discharge, which could result in loss of ability to safely control a CMV. See the Evidence Report on Cardiovascular Disease and Commercial Motor vehicle Driver Safety, April 2007.¹ A focused research report on Implantable Cardioverter Defibrillators and the Impact of a Shock on a Patient When Deployed completed for the FMCSA December 2014 indicates that the available scientific data on

¹ Now available at http://ntl.bts.gov/lib/30000/30100/30123/Final_CVD_Evidence_Report_v2.pdf

persons with ICDs and CMV driving does not support that persons with ICDs who operate CMVs are able to meet an equal or greater level of safety and upholds the findings of the April 2007 report.

Discussion of Public Comments

On April 21, 2015, FMCSA published in a **Federal Register** Notice, the names of 15 individuals requesting ICD exemption and requested public comment. The public comment period closed on May 21, 2015. A total of 29 commenters responded to the notice. The majority of commenters were in favor of the applicants continuing to drive CMV's with ICD's. Commenters believed that the individuals seeking exemptions were responsible drivers who had safe driving histories and were compliant with their medical treatment programs. One anonymous commenter encouraged the FMCSA not to grant these individuals exemptions due to concerns of the risks of the underlying medical conditions in combination with operating a commercial motor vehicle.

FMCSA's Response

FMCSA acknowledges the commenters' reports of medical compliance and safe driving histories of the applicants. However, based on the available medical literature and data, FMCSA believes that drivers with an ICD are at risk for incapacitation if the device discharges in response to cardiovascular symptoms. This risk is combined with the risks associated with the underlying cardiovascular condition for which the ICD has been implanted as a primary or secondary preventive measure.

Mr. Leslie Mitchell no longer has a functioning ICD and may operate CMVs in interstate commerce based on the decision of the medical examiner. Mr. Mitchell has a pacemaker/ICD but the ICD portion was disabled because his cardiologist determined he no longer needs tachycardia therapy. Therefore, if a medical examiner determines that he

meets the cardiovascular standard and all other physical qualification standards for operating a commercial motor vehicle in interstate commerce, he may be issued a medical certificate.

Conclusion

FMCSA evaluated the remaining 14 of 15 individual exemption requests on their merits, available data from Evidence Reports and Medical Expert Panel opinions on ICDs and commercial motor vehicle driving, and the public comments received. The Agency has determined that the available medical literature and data does not support a conclusion that granting these exemptions would achieve a level of safety equivalent to or greater than, the level of safety maintained without the exemptions. Each applicant has, prior to this notice, received a letter of final disposition on his/her exemption request. Those decision letters fully outlined the basis for the denial and constitute final Agency action. The list published today summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

The following 14 applicants are denied exemptions from the cardiovascular standard concerning ICDs.

Craig Bohms

Daniel Donahue

James Dean

Bernard Fritzson

Terry Goodhile

Ronald Heinlein

David Allan Jensen

Douglas Lopez

Michael Politz

Mark Register

Charles Rhodes

Stephen Watts

Mark Steiner

John Allen Weltz

Issued on: October 15, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015-27210 Filed: 10/23/2015 08:45 am; Publication Date: 10/26/2015]